

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  1108.1003									
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]  on _____  Signature _____  Typed or printed name _____		Application Number  10/596,267	Filed  February 7, 2007								
		First Named Inventor  Giammona, G.									
		Art Unit  1616	Examiner  Browe, D.								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%; border: none;"><tr><td style="width: 50%; vertical-align: top; padding: 5px;"><input type="checkbox"/> applicant/inventor.</td><td style="width: 50%; vertical-align: top; padding: 5px; text-align: right;">/Silvia Salvadori/ _____ Signature</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td style="vertical-align: top; padding: 5px; text-align: right;">Silvia Salvadori _____ Typed or printed name</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input checked="" type="checkbox"/> attorney or agent of record. Registration number 48,265</td><td style="vertical-align: top; padding: 5px; text-align: right;">646-783-6758 _____ Telephone number</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td style="vertical-align: top; padding: 5px; text-align: right;">November 16, 2010 _____ Date</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<input type="checkbox"/> applicant/inventor.	/Silvia Salvadori/ _____ Signature	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	Silvia Salvadori _____ Typed or printed name	<input checked="" type="checkbox"/> attorney or agent of record. Registration number 48,265	646-783-6758 _____ Telephone number	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	November 16, 2010 _____ Date
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<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.											

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**UNITED STATES PATENT & TRADEMARK OFFICE**

Art Unit : 1616 Confirmation No.: 4701  
Applicant : Giammona et al.  
Serial No. : 10/596,267  
Filed : February 7, 2007  
Examiner : Browe D.

For: **ANIONIC HYDROGEL MATRICES WITH PH  
DEPENDENT MODIFIED RELEASE AS DRUG CARRIERS**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Pre-Appeal Brief**

Sir:

Applicants submit this Pre-Appeal Brief together with a Notice of Appeal in response to the Final Office Action of August 16, 2010. Thus, this Pre-Appeal Brief is timely filed.

## REMARKS

The pending claims 1, 5-15 and 17-19 are the subject of Applicants' appeal. The presently claimed invention is directed to:

Anionic hydrogel matrixes obtained by chemical reticulation by means of irradiation of copolymers containing photoreticulable groups, wherein the photoreticulable groups are derived from insertion of glycidyl methacrylate (GMA) and methacrylic anhydride (MA) in the side chain of PHEA in the presence of acid comonomers.

(*e.g.*, page 3, lines 1-14).

The Examiner has rejected claims 1, 5-15 and 17-19 under 35 U.S.C. § 103(a) for allegedly being obvious over Bromberg et al. (U.S. Patent Application Publication No. 20030152623, hereinafter "Bromberg") in view of Blum et al. (U.S. Patent No. 6,294,591, hereinafter "Blum"), Giammona et al. (Biochimica et Biophysica Acta, 1999, hereinafter "Giammona") and Cavazza (U.S. Patent No. 6,013,670, hereinafter "Cavazza").

As submitted in the After Final Amendment of November 2, 2010 and on the response filed on July 26, 2010, Bromberg does not provide for the specific polyaspartamide derivatized polymers, but it discloses a plethora of suitable polymers (*e.g.*, November 2, 2010 After Final Amendment, page 7, lines 3-10).

As also submitted on November 2, 2010, Blum is completely silent with regard to PHEA and it only teaches that it is possible to form polymers with reactive side groups (*e.g.*, November 2, 2010 After Final Amendment, page 7, lines 13-14). Because Blum only relates to polymers known and used for preparing radiation-curable coatings, paints, adhesives etc, Blum is not analogous to the field of Applicants' endeavor (MPEP § 2141.01(a)). Thus, unlike in *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008) ("analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for applicant's purpose"), one skilled in

the art would not even consider the teachings of the Blum reference.

Moreover, the Examiner's characterization of Blum on page 12 of the Final Office Action is erroneous and out of context. The Examiner reported that on col. 3, lines 36-39 Blum notes that *"the selection of monomers for combination is made in accordance with principles familiar to the skilled worker, such that they satisfy the requirements of the envisaged application"* and that *"these requirements may differ greatly"*. However, Applicants submit that this sentence is incomplete and taken out of context. On col. 3, lines 39-43, Blum continues the citation *"for example, transparent automotive topcoats for metallic finishes are required to have very high resistance to yellowness and weathering, high scratch resistance and good gloss retention coupled with high hardness."* Thus, the Examiner's conclusion that a person of ordinary skill in the pharmaceutical arts would thus readily recognize and be able to take advantage of the relevant teachings the Blum reference affords to the pharmaceutical arts is completely erroneous. Blum provides no teachings whatsoever with regard to the pharmaceutical art.

Accordingly, one person of skills in the pharmaceutical art would never even consider the teachings of Blum, which, unlike the Examiner conclusion at the bottom of page 12 of the Final Office Action, cannot provide for the deficiencies of Bromberg. Thus, it necessary follows that also the Examiner's' comment on page 13 of the Final Office Action (*e.g.*, lines 5-10) becomes irrelevant. In other words, since Blum cannot be considered as a relevant reference to support a *prima facie* obviousness rejection, it cannot provide for Giammona's missing link. As such, since Giammona is completely silent with regard to PHEA derivatisable with GMA and MA, the combination of Bromberg with Blum and Giammona still does not disclose all of the claimed limitations.

It is settled law that obviousness can be established by combining or modifying the

teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so. *In re Kahn*, 441, F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). As set forth above, Blum provides no motivation to one skilled in the art to insert MA into PHEA photo-crosslinked by insertion of GMA into the side chains. On the contrary, Blum is not analogous to the field of Applicants' invention and does not provide any useful teaching for the person of skill in the pharmaceutical art.

Moreover, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007). The simple reason that Blum and Giammona can be combined is not enough to render obvious the claimed subject matter because one of ordinary skill in the art would not even have considered Blum as a relevant reference to be combined with Giammona.

Further, a statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill in the art at the time the claimed invention was made” because the references relied upon teach all aspects of the claimed invention were individually known in the art, is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

Thus, the Examiner's statement that it was established and disclosed at the time of the present application that PHEA could be photo-crosslinked by insertion of GMA into the side chain and thus, any person of ordinary skill in the art would find it obvious from the disclosure of Blum to insert MA as well, is not enough to establish a *prima facie* case of obviousness. No objective reasons or motivations have been provided to explain why such teachings should be combined.

Finally, the subject matter of claim 1 and of all of the claims depending from it, except for claim 18, does not mention any L-carnitines. Thus, Cavazza is completely irrelevant with regard to the subject matter of claims 1, 5-15 and 19. However, since the combination of Bromberg with Blum and Giammona would not have rendered obvious the subject matter of any of the pending claims, it is respectfully submitted that claim 17 is also patentable over the combination of the cited references even in view of Cavazza.

Thus, for all of the reasons set forth above, it is respectfully submitted that the Examiner's alleged combination would not have rendered obvious the subject matter of the pending claims to one skilled in the art.

Thus, Applicants respectfully submit that the Examiner's rejection is untenable and should be overturned.

For the foregoing reasons, it is respectfully submitted that this Application is in condition for an allowance and reconsideration and allowance are respectfully requested.

Should any extensions of time or fees be necessary in order to maintain this Application in pending condition, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 02-2275.

Dated: November 16, 2010

Respectfully submitted,

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